UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK

APRIL BARHYDT, an individual,
Plaintiff,

vs.

MUTUAL PHARMACEUTICALS, INC., UNITED RESEARCH LABORATORIES, PHARMACEUTICAL HOLDINGS CORP., AR SCIENTIFIC, INC., AR HOLDING COMPANY, INC.,
Defendants.

COMPLAINT AND DEMAND FOR JURY TRIAL

'08 CIV 5140

Plaintiff, April Barhydt, by and through her attorneys, WEITZ & LUXENBERG, P.C. and ANDREWS & THORNTON, at all relevant times hereinafter mentioned, alleges as follows:

JURIDICTION AND VENUE

The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. 1332 because complete diversity exists between Plaintiff who is a citizen of New York which is different from the States where the defendants are incorporated and have their principal place of business, and the amount in controversy for the plaintiff exceeds $75,000, exclusive of interest and costs.

Venue is proper within this District pursuant to 28 U.S.C. 1391 because a substantial part of the events or omissions giving rise to the claim occurred in this district, as well as any defendant resides here in accordance with 28 U.S.C. 1391 (a) and (c).

THE PARTIES

1. Plaintiff April Barhydt is currently, and at all times relevant hereto was, a resident and citizen of the State of New York and currently resides at 35 Purse Lane, Hopewell Junction, New York 12533.

2. Defendant Mutual Pharmaceuticals, Inc. (MUTUAL) is, and at all times relevant was, a Corporation organized under the laws of the State of Pennsylvania, with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124. On information and belief, MUTUAL performs business in the State of New York either directly or through its wholly owned and controlled subsidiaries.

3. Defendant United Research Laboratories (URL) is, and at all times relevant was, a Corporation organized under the laws of the State of Pennsylvania, with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124. On information and belief, URL performs business in the State of New York either directly or through its wholly owned and controlled subsidiaries.

4. Defendant Pharmaceutical Holdings Corp. (PHARMACEUTICAL HOLDINGS) is, and at all times relevant was, a Corporation organized under the laws of the State of Pennsylvania, with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania 19124. On information and belief, PHARMACEUTICAL HOLDINGS performs business in the State of New York either directly or through its wholly owned and controlled subsidiaries.

5. Defendant AR Scientific, Inc. (AR SCIENTIFIC) is, and at all times relevant was, a Corporation organized under the laws of the State of Pennsylvania, with its principal place of business at 1100 Orthodox Street, Philadelphia, Pennsylvania

19124. On information and belief, AR SCIENTIFIC performs business in the State of New York either directly or through its wholly owned and controlled subsidiaries.

6. Defendant AR Holding Company, Inc. (AR HOLDING) is, and at all times relevant was, a Corporation organized under the laws of the State of Delaware, with its principal place of business at 1105 N. Market Street, Suite 1300, Wilmington, Delaware 19801. On information and belief, AR HOLDING performs business in the State of New York either directly or through its wholly owned and controlled subsidiaries.

7. Defendants MUTUAL and URL are wholly owned subsidiaries of PHARMACEUTICAL HOLDINGS.

8. Defendants MUTUAL, AR SCIENTIFIC, and AR HOLDING are pharmaceutical companies who are, and at all times herein alleged were, in the formulation, marketing, sale, and distribution of drug products containing quinine sulfate (quinine).

9. Defendants URL and PHARMACEUTICAL HOLDINGS, on information and belief, at all times herein alleged, are involved in the marketing, distribution, and sale of drug products containing quinine.

FACTUAL BACKGROUND

10. The causes of action hereinafter are brought to recover compensatory and punitive damages based on strict products liability, failure to warn, negligence, and breach of implied and express warranties, punitive damages, and violation of New York General Business Law Section 349.

11. The Food, Drug and Cosmetic Act (FDCA) of 1938 gave authority to the Food and Drug Administration (FDA) to oversee the safety of drugs and specifically

required new drugs to be tested for safety before marketing and required drugs to have adequate labeling for safe use.

12. The FDCA contained a "grandfather clause" which permitted drugs, such as quinine, in use before 1938 to be sold over-the-counter (OTC) without submitting a New Drug Application (NDA) to the FDA.

13. Quinine has been used to treat malaria and it has also been used for the treatment and prevention of the far less serious medical condition of nocturnal leg muscle cramps and related conditions.

14. In 1972, the FDA undertook a review of the safety and effectiveness of the grandfathered drugs such as quinine. Drugs which were determined by the FDA to be not generally recognized as safe and effective (GRASE) were ruled to be "new drugs" and "misbranded" so that they could no longer be marketed without an NDA.

15. In 1994, as a part of the review process, the FDA published a final rule in the Code of Federal Regulations prohibiting the sale of quinine for the treatment of nocturnal leg cramps without approval of an NDA.

16. Additionally, in 1995, the FDA ordered a stop to the marketing of quinine for nocturnal leg cramps and sent warning letters to 44 companies stating that it is unlawful to market their quinine sulfate products for nocturnal leg cramp relief because even under a doctor's care, the risks of quinine use outweighs any possible benefits.

17. The FDA published its serious health concerns about the toxicity of quinine in the Federal Register. The FDA stated that it had received reports between 1969 and 1992 of 156 serious health problems from quinine use including 23 quinine-induced injuries that resulted in death. These potentially dangerous and

deadly quinine-induced conditions included: cardiac arrhythmia, renal failure, liver failure, blindness, hearing loss and blood disorders including thrombotic thrombocytopenia purpura (TTP) and thrombocytopenia (quinine-induced conditions).

18. The FDA has recognized that the illegal sale of drugs such as quinine is a public health problem because of confusion amongst healthcare providers about such non-FDA approved drugs:

> [F]or a variety of historical reasons, some drugs, mostly older products, *continue to be marketed illegally* in the United States without required FDA approval. (Emphasis added.)
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> * * *
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> Many healthcare providers are unaware of the unapproved status of some drugs and have continued to unknowingly prescribe unapproved drugs because the drugs' labels do not disclose that they lack FDA approval. Often these drugs are advertised in reputable medical journals or are included in widely used pharmaceutical references such as the Physicians' Desk Reference (PDR). "Drugs Marketed in the United States That Do Not Have Required FDA Approval," U.S. Food and Drug Administration Website, http://www.fda.gov/cder/drug/unapproved_drugs/default.htm (2006).

19. The FDA approved an NDA, submitted by MUTUAL for the prescription use of quinine on August 12, 2005. The FDA approval of the MUTUAL NDA was for the treatment of only one disease, uncomplicated malaria.

20. The approval of the MUTUAL's NDA required MUTUAL to sell quinine with a specific product label. The product label required a warning that quinine is not approved for the treatment of nocturnal leg cramps: "Qualaquin oral capsules are not approved for the treatment of prevention of nocturnal leg cramps." The WARNINGS

section of the label contains strong language against the use of quinine for nocturnal leg cramps:

> "Qualaquin may cause unpredictable serious and life-threatening hypersensitivity reactions, QT prolongation, serious cardiac arrhythmias including torsades de points, and other serious adverse events requiring medical intervention and hospitalization. Fatalities have also been reported. The risk associated with the use of Qualaquin in the absence of evidence of its effectiveness for treatment or prevention of nocturnal leg cramps, outweighs any potential benefit in treating, and/or preventing this benign, self limiting condition..."

21. Defendants promoted, marketed, and sold quinine knowing that it was primarily prescribed and used for treatment of nocturnal leg cramps.

22. On information and belief, it is alleged that the label for the quinine sold by Defendants failed to disclose that the FDA had found that quinine had an unfavorable risk benefit ratio for the treatment of nocturnal leg cramps.

23. Defendants promoted, marketed, and sold quinine a without product label comparable to the product label required for the sale of the MUTUAL product in reckless and conscious disregard of the health and public safety of consumers. Said Defendants knew that some consumers taking their quinine product for treatment of nocturnal leg cramps would become seriously ill or die.

24. It was illegal, at all times herein alleged, for Defendants to market, sell, or distribute quinine for the treatment of nocturnal leg cramps.

25. Defendants had control of the packaging, marketing, advertising, manufacturing, labeling, promotion, distribution, and sales of their quinine product, including the product purchased by the Plaintiff April Barhydt alleged herein.

26. At all times material hereto, each of the Defendants acted individually and also by and through each of the other Defendants, as well as by and through those Defendants' agents, servants, employees, apparent agents, and ostensible agents as described more fully herein.

27. All acts and/or failures of Defendants and each of them were done or not done by their respective agents, servants, work persons, and/or employees, and were conducted within the scope and course of their employment and authority on behalf of Defendants.

28. The herein mentioned personal injuries of Plaintiff April Barhydt were caused by the negligence and carelessness of all named Defendants, acting individually or in concert, and of their agents, servants, employees, apparent agents, and ostensible agents, all acting within and during the course and scope of their employment, authority, and/or apparent authority.

29. Plaintiff April Barhydt was not aware of the risks associated with quinine and could not, through the exercise of reasonable diligence, discover the risks. Had the Plaintiff April Barhydt known the dangers and risks associated with quinine, she would not have taken quinine for the treatment of nocturnal leg cramps.

PLAINTIFF – APRIL BARHYDT

30. On or about May 27, 2005, Plaintiff April Barhydt was prescribed quinine by her physician for leg cramps.

31. At the time the physicians wrote the prescriptions for Plaintiff April Barhydt, on information and belief, they reasonably believed that quinine had been approved by the FDA for use in the treatment of leg cramps, and further believed that

the FDA had approved the sale of quinine as a prescription drug for treatment of leg cramps after the FDA weighed the risks versus the benefits and had concluded that the benefits exceeded the risks. Neither plaintiff's physicians nor any other reasonable healthcare provider would have prescribed quinine for treatment of leg cramps had they understood the true facts of the FDA's findings.

32. On or about May 27, 2005, Plaintiff April Barhydt purchased quinine at a CVS in Hopewell Junction, New York.

33. The quinine purchased by Plaintiff April Barhydt on or about May 27, 2005, was manufactured, marketed and sold by the Defendants in the ordinary course of their business.

34. On or about May 27, 2005 when Plaintiff April Barhydt purchased the product, it was being sold in violation of the federal and state drug laws.

35. Plaintiff April Barhydt ingested quinine as needed for the treatment of nocturnal leg cramps as directed by her physician. She took the quinine as directed. On or about June 4, 2005, as a result of the ingestion of quinine sold by the Defendants, and each of them, Plaintiff April Barhydt developed quinine-induced immune thrombocytopenia and other quinine-induced conditions.

36. As a direct and proximate result of the wrongful actions of each of the Defendants, Plaintiff April Barhydt suffered from quinine-induced immune thrombocytopenia and other quinine-induced conditions which required her to be hospitalized and treated with invasive medical procedures. Plaintiff April Barhydt has paid and/or incurred and will incur in the future hospital and medical expenses in amounts which shall be proven at the time of trial.

37. As a direct and proximate result of the wrongful actions of each of the Defendants and of the injuries to Plaintiff April Barhydt resulting therefrom, Plaintiff April Barhydt has incurred loss of earnings and earning capacity.

38. As a direct and proximate result of the wrongful actions of each of the Defendants and of the injuries to Plaintiff April Barhydt resulting therefrom, this caused Plaintiff April Barhydt to suffer from physical and emotional pain, fear and anxiety, and anguish.

COUNT I: STRICT PRODUCTS LIABILITY
(AGAINST ALL DEFENDANTS)

39. Plaintiff April Barhydt incorporates, by reference, all other paragraphs of this Complaint.

40. At all times material to this action, Defendants engaged in the business of marketing, sale, and distribution of quinine for treatment of leg cramps, which is defective and unreasonably dangerous to consumers, including the Plaintiff April Barhydt.

41. Quinine was expected to reach, and did reach, via the stream of commerce, consumers, including the Plaintiff April Barhydt, without substantial change in the condition in which it was sold.

42. Defendants knew and intended that their product would be purchased from retail drug stores and pharmacies, including CVS, by members of the general public, and would be prescribed by physicians in reliance on the representations made by such Defendants on the product label and in other promotional and sales materials.

43. Plaintiff April Barhydt alleges, on information and belief, that quinine was defective and unreasonably dangerous when it left the possession of Defendants in that

it contained warnings insufficient to alert physicians and/or consumers, including the Plaintiff, of the risks and reactions associated with utilization of quinine in the treatment of nocturnal leg cramps.

44. Plaintiff April Barhydt used quinine for its intended, foreseeable and knowable purpose, the treatment of leg cramps.

45. Plaintiff April Barhydt could not have discovered any defects in the drug through the exercise of reasonable care or diligence.

46. Defendants are manufacturers, marketers, sellers, and distributors of quinine and are held to the level of knowledge of experts in the field.

47. The warnings given by the Defendants were not accurate, thorough, clear or unambiguous. Specifically, neither the Plaintiff or her doctors were warned that such quinine was sold without FDA approval, that the FDA had made a finding based upon its review of the data, that quinine was not safe and effective for the treatment of nocturnal leg cramps, that the risks of quinine outweigh the benefits for the treatment of nocturnal leg cramps, or that quinine was unreasonably dangerous for treatment of nocturnal leg cramps. The labeling of the quinine marketed by said Defendants was inadequate and failed to provide necessary warnings because it did not contain the use and safety information required by state and federal law and did not clearly disclose a number of serious and deadly quinine-induced conditions.

48. Defendants had a continuing duty to warn the Plaintiff April Barhydt of the safe indications for the use of quinine of the dangers associated with the use of quinine.

49. The actions of Defendants described above, were performed wilfully, intentionally, and with reckless disregard for the rights and safety of the Plaintiff April

Barhydt and the public. Said Defendants at all times herein knew that by marketing and selling quinine for the treatment of leg cramps that some consumers would be afflicted by quinine-induced conditions and would thereby suffer serious injury and death.

50. As a direct and proximate result of the defective condition of quinine, Plaintiff April Barhydt suffered serious personal injuries and was and will be caused to expend monies for medical care from quinine-induced conditions.

WHEREFORE, Plaintiff demands judgment against each defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court and jury deem proper.

COUNT II: NEGLIGENCE

51. Plaintiff April Barhydt incorporates, by reference, all other paragraphs of this Complaint.

52. Defendants had a duty to use reasonable care to assure that the drug products they sell, including quinine, were sold in compliance with state and federal drug laws and to adequately warn of the dangers of their products.

53. On and before the time of sale to the Plaintiff April Barhydt, as herein alleged, Defendants knew, and/or in the exercise of reasonable care should have known, but failed to disclose to consumers, physicians and distributors and thereby breached their duty to warn that quinine was unreasonably dangerous for the treatment of nocturnal leg cramps, that quinine had not been approved by the FDA for the treatment of nocturnal leg cramps, and that the sale of quinine for nocturnal leg cramps was a violation of state and federal drug laws. Such defendants also failed to disclose

that the experts at FDA had made a finding that the risk of the use of quinine for treatment of nocturnal leg cramps outweighed the benefits.

54 On and before the time of sale to the Plaintiff April Barhydt, as herein alleged, Defendants knew, and/or in the exercise of reasonable care should have known, but failed to disclose serious and deadly quinine-induced conditions.

55. Defendants negligently, carelessly, and recklessly formulated, marketed, labeled, sold, and distributed quinine in violation of the federal and state drug laws.

56. Defendants, and each of them, knew or should have known that consumers, such as Plaintiff April Barhydt could foreseeably suffer injury as a result of Defendants' failure to exercise reasonable care and discharge their legal duties as described above.

57. As a direct and proximate result of the negligence of Defendants, and each of them, Plaintiff April Barhydt suffered from quinine-induced conditions.

58. Defendants' conduct was reckless, without regard for the public's safety and welfare, beyond all standards of conduct and decency and was akin to wilful misconduct and the Defendants misled the public at large, including the Plaintiff and her physicians, by making false representations about the safety of their product and its approved indications.

WHEREFORE, Plaintiff demands judgment against each defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court and jury deem proper.

COUNT III: BREACH OF EXPRESS AND IMPLIED WARRANTIES

59. Plaintiff April Barhydt incorporates, by reference, all other paragraphs of this Complaint.

60. At the time and place of the sale, distribution and supply of Defendants' quinine product, Defendants expressly represented and warranted that the product was safe, and impliedly warranted that the product was reasonably fit for its intended purpose, the treatment of nocturnal leg cramps. However, the product was unfit and unsafe for that purpose.

61. At the time and place of manufacture and sale, the product was not reasonably fit for its intended purpose, was not of marketable quality, and constituted an extreme hazard and danger to persons using said product. Thus, Defendants breached an implied warranty pursuant to U.C.C. 2-314. The Defendants also breached the implied warranty of fitness for a particular purpose (U.C.C. 2-315). Defendants also breached these warranties by failing to warn of known or readily ascertainable risks associated with their quinine product.

WHEREFORE, Plaintiff demands judgment against each defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court and jury deem proper.

COUNT IV: VIOLATION OF NEW YORK GENERAL BUSINESS LAW SECTION 349

62. Plaintiff April Barhydt incorporates, by reference, all other paragraphs of this Complaint.

63. Defendants engaged in commercial conduct by selling quinine. Defendants misrepresented and omitted material information regarding quinine by failing to disclose known risks and the fact that nocturnal leg cramps were not an approved indication.

64. By failing to disclose the known dangers and risks of quinine, Defendants engaged in unfair and deceptive consumer-oriented acts.

65. Reasonable consumers, including plaintiff, were injured by Defendants' unfair and deceptive acts.

66. As a direct and proximate result of Defendants' conduct, plaintiff has suffered actual damages and requests an award of damages against Defendants, as authorized by New York General Business Law § 349, et seq. Plaintiff is entitled to statutory damages, punitive damages, costs and reasonable attorneys' fees, plus disgorgement of any profits Defendants earned as a result of their violations of law.

WHEREFORE, Plaintiff demands judgment against each defendant, individually, jointly and severally for compensatory damages in a sum in excess of $75,000 and punitive damages, together with interest, costs of suit, attorneys' fees and all such other and further relief as the Court and jury deem proper.

RELIEF REQUESTED

WHEREFORE , Plaintiff demands judgment against Defendant as follows:

(a) compensatory damages on each cause of action in an amount in excess of seventy-five thousand dollars ($75,000);

(b) punitive damages on each cause of action;

(c) awarding reasonable attorneys' fees, expert fees, costs and interest;

(d) disgorgement of any profits Defendants earned as a result of violations of New York General Business Law § 349, et. seq; and

(e) granting such additional and further relief as the Court deems just and proper.

DEMAND FOR JURY TRIAL

Plaintiff April Barhydt hereby demands a jury trial on all causes of action asserted herein.

Dated: New York, New York
June 4, 2008

Yours, etc.,

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By: _____
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